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ANDERSON et al.
AMENDMENT AND RESPONSE

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members **302** and **304** of the housing and the test strip **100**. Also shown are the sample application port **306**, test window **308**, and the optionally included bar code **316**. Also shown are an aperture **306** above the detection and control zones, the upper surface **308** of upper member **302**, an end **310** used for gripping the housing, and a sample window **312**.

IN THE CLAIMS:

Please cancel claim 10 without prejudice or disclaimer.

Please add claims 16-30 as follows:

- Sub E1
Sub 115
16. (New) The method of claim 1, further comprising:
determining a parameter correlated with an intensity or shape of the image.
17. (New) The method of claim 1, further comprising:
moving the reader head to a second position;
measuring a fourth amount of light reflected from the second position on the surface comprising the image;
uniformly illuminating the second position on the surface with light of the first wavelength, and measuring a fifth amount of light reflected from the surface;
uniformly illuminating the second position on the surface with light of the second wavelength, and measuring a sixth amount of light reflected from the surface; and
determining a parameter correlated with an intensity or shape of the image.
- C2
18. (New) The method of claim 1, further comprising:
repeating each of the measuring and illuminating steps at additional positions on the surface until the image on the surface of the test strip is scanned; and
determining an intensity or shape of the image.

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Sub E1
19. (New) A method for reading a surface of a test strip comprising an image, comprising:

moving a reader head in a reflectance reader to a first position over the surface comprising the image;

measuring a first amount of light reflected from the surface comprising the image;

transmitting light of a first wavelength onto the surface at an angle normal to the surface, and measuring a second amount of light reflected normally from the surface; and

transmitting light of a second wavelength onto the surface at an angle normal to the surface, and measuring a third amount of light reflected normally from the surface.

Sub P6
20. (New) A method for reading a surface of a test strip comprising an image, comprising:

with a reader head in a reflectance reader at a first position over the surface comprising the image, measuring a first amount of light reflected from the first position of the surface comprising the image;

transmitting light of a first wavelength onto the first position of the surface at an angle normal to the surface, and measuring a second amount of light reflected normally from the surface;

transmitting light of a second wavelength onto the first position of the surface at an angle normal to the surface, and measuring a third amount of light reflected normally from the surface;

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moving the reader head to a second position over the surface comprising the image;

measuring a fourth amount of light reflected from the second position on the surface comprising the image;

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transmitting light of the first wavelength onto the second position of the surface at an angle normal to the surface, and determining a fifth amount of light reflected normally from the surface;

transmitting light of the second wavelength onto the second position of the surface at an angle normal to the surface, and determining a sixth amount of light reflected normally from the surface; and

determining a parameter correlated with an intensity or shape of the image.

21. The method of claim 1, further comprising moving the reader head in a stepwise fashion to a plurality of positions over the test strip, wherein three light measurements are made at each of the plurality of positions to determine an intensity or shape of the image.

22. The method of claim 1, wherein the step of measuring a first amount of light is carried out while no light is produced by a light source in the reader head.

23. The method of claim 1, wherein the first wavelength is blue.

24. The method of claim 1, wherein the second wavelength is amber.

25. The method of claim 1, wherein the measuring the first amount of light is used to determine an amount of background light.

26. The method of claim 1, wherein the measuring the second amount of light is used to determine levels of light reflections associated with the background of the bar code or the assay test strip.

27. The method of claim 1, wherein the measuring the third amount of light is used to detect a symbology or the presence of an analyte on the test strip.

C2
28. The method of claim 1, further comprising one or more steps selected from the group consisting of: (1) using the light measurements to correct for light leakage; (2) reducing the light measurements using a ratiometric formula; (3) reducing the light measurements using a neural network; (4)

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Sub E1
creating a generated image of test data by plotting reduced light measurements; (5) expressing a generated image as a polynomial mathematical function; (6) using a curve-fitting algorithm to generate parameters to define a generated image; (7) optimizing a reconstruction of a generated image and producing a fitted image; (8) comparing light measurements and fitted image by solving the linear regression; (9) validating one or more parameters obtained from linear regression and one or more peak heights obtained; (10) classifying a validated result as positive or negative by comparing peak heights of a clinical sample to reference samples; (11) classifying a result using a neural network; and (12) using a test result with other patient information in a decision-support system to generate a medical diagnosis or risk assessment.

Sub 7
29. The method of claim 1, further comprising
emitting the light of the first wavelength from a light emitting diode;
transmitting the emitted light of the first wavelength through a first fiberoptic bundle to the surface of the test strip; and
transmitting the second amount of light reflected from the surface of the test strip through a second fiberoptic bundle to a photodetector.

30. The method of claim 1, further comprising
emitting the light of the first wavelength from a light emitting diode;
transmitting the emitted light of the first wavelength through a first fiberoptic bundle to the surface of the test strip; and
transmitting the second amount of light reflected from the surface of the test strip through a second fiberoptic bundle to a photodetector.
emitting the light of the second wavelength from a light emitting diode;
transmitting the emitted light of the second wavelength through a third fiberoptic bundle to the surface of the test strip; and

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C2 amended
transmitting the third amount of light reflected from the surface of the test strip through a second fiberoptic bundle to the photodetector.

Please replace claims 1-9 and 11-14 with amended claims 1-9 and 11-14 as follows:

Sub E1
1. (Amended Twice) A method for reading a surface of a test strip comprising an image, comprising:

moving a reader head in a reflectance reader to a first position over the surface comprising the image;

measuring a first amount of light reflected from the surface comprising the image;

uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface; and

uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface.

2. (Amended Twice) The method of claim 1, wherein the reader head comprises:

a reader head body;

a light emitting diode;

a first fiberoptic bundle optically coupled to the light emitting diode;

a photodetector;

a second fiberoptic bundle optically coupled to the photodetector;

an aperture in the reader head body; and

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a plurality of fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture, wherein: a first portion of the fiberoptic conductor ends comprises fiberoptic conductors of the first fiberoptic bundle; and a second portion of the fiberoptic

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conductor ends comprises fiberoptic conductors of the second
fiberoptic bundle.

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3. (Amended) The method of the claim 1, wherein the reflectance reader
further comprises,

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a control unit including a processor modified with a software subsystem,
wherein the software subsystem is for analyzing data produced in the steps of
determining the first, second and third amounts of light reflected from the
surface.

4. (Amended) The method of claim 1, further comprising performing an
immunoassay on the test strip.

5. (Amended Three Times) The method of claim 1, wherein the
reflectance reader comprises:

the reader head comprising:

a reader head body;

a light emitting diode;

a first fiberoptic bundle optically coupled to the light emitting diode,
and adapted to transmit light from the light emitting diode;

a photodetector adapted for generating a reflection signal in
response to reflected light;

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a second fiberoptic bundle optically coupled to the photodetector,
and adapted to transmit an amount of reflected light to the photodetector;

an aperture in the reader head body; and

a plurality of fiberoptic conductor ends arranged in a sigmoidal
distribution in the aperture, wherein: a first portion of the fiberoptic conductor
ends comprises fiberoptic conductors of the first fiberoptic bundle; and a second
portion of the fiberoptic conductor ends comprises fiberoptic conductors of the
second fiberoptic bundle, the plurality of fiberoptic conductor ends being further
arranged in a substantially co-planar relationship; and a reader housing
comprising:

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a housing body, and
a cassette slot adapted to receive a test device.

Sub E1
6. (Amended) The method of the claim 5, wherein the reflectance reader further comprises,
a control unit including a processor modified with a software subsystem, wherein the software subsystem is for analyzing data produced from the steps of determining the first, second and third amounts of light reflected from the surface.

7. (Amended) The method of claim 5, further comprising performing an immunoassay on the test strip.

8. (Amended) The method of claim 1, further comprising determining a parameter correlated with the intensity or shape of the image, wherein the parameter is the amount of an analyte in a sample, which is a function of the first amount of light reflected, the second amount of light reflected, and the third amount of light reflected.

9. (Amended) The method of claim 1, wherein the method further comprises determining an amount of an analyte in a sample by correlating the parameter with the amount of analyte in the sample.

Sub A3
11. (Amended Twice) The method of claim 1, wherein said first wavelength is selected to reflect equally from all regions of the test strip, whereby said second amount of light is indicative of a test region of test strip.

C7
12. (Amended Twice) The method of claim 1, wherein said second wavelength reflects substantially optimally from a test region of the test strip, whereby said third amount of light is indicative of an amount of a label at the test region.

13. (Amended) The method of claim 1, further comprising determining an amount of an analyte in a sample, wherein the analyte is fetal fibronectin.

C8
14. (Amended) The method of claim 5, further comprising determining an amount of an analyte in a sample, wherein the analyte is fetal fibronectin.